EXHIBIT B

Gynecare

PROLIFT+M™

Total Pelvic Floor Repair System
Anterior Pelvic Floor Repair System
Posterior Pelvic Floor Repair System

جهاز إصلاح قاع الحوض بالكامل
جهاز إصلاح الجزء الأمامي من قاع الحوض
جهاز إصلاح الجزء الخلفي من قاع الحوض

Сістэма поўнай рэканструкцыі лагвовага дна
Сістэма рэканструкцыі пярэдняга абсягу лагвовага дна
Сістэма рэканструкцыі задняга абсягу лагвовага дна

Система за цялостна реконструкция на тазовото дъно
Система за реконструкция на предната част на тазовото дъно
Система за реконструкция на задната част на тазовото дъно

Systém pro celkovou rekonstrukci pánevního dna
Systém pro rekonstrukci přední části pánevního dna
Systém pro rekonstrukci zadní části pánevního dna

Totalt reparationssystem til bækkenbunden
Reparationssystem til anteriore bækkenbund
Reparationssystem til posteriore bækkenbund

Bekkenbodemreparatiesysteem totaal
Bekkenbodemreparatiesysteem anterieur
Bekkenbodemreparatiesysteem posterieur

Vaagnapõhja rekonstruktsiooni täissüsteem
Vaagnapõhja eesosa rekonstruktsiooni süsteem
Vaagnapõhja tagaosa rekonstruktsiooni süsteem

Totaalinen lantionpohjan korjausjärjestelmä
Anteriorinen lantionpohjan korjausjärjestelmä
Posteriorinen lantionpohjan korjausjärjestelmä

Système de reconstruction complète du plancher pelvien
Système de reconstruction antérieure du plancher pelvien
Système de reconstruction postérieure du plancher pelvien

Totalprolaps-Beckenboden-Rekonstruktionssystem
Anteriores Beckenboden-Rekonstruktionssystem
Posteriores Beckenboden-Rekonstruktionssystem

Σύστημα ολικής αποκατάστασης πυελικού εδάφους
Σύστημα αποκατάστασης πρόσθιου πυελικού εδάφους
Σύστημα αποκατάστασης οπίσθιου πυελικού εδάφους

Teljes medencefenék-rekonstrukciós rendszer
Mellső medencefenék-rekonstrukciós rendszer
Hátsó medencefenék-rekonstrukciós rendszer

Sistema di riparazione totale del pavimento pelvico
Sistema di riparazione anteriore del pavimento pelvico
Sistema di riparazione posteriore del pavimento pelvico

Жамбас түбінің толық қалпына келтіру жүйесі
Алдынғы жамбас түбін қалпына келтіру жүйесі
Артқы жамбас түбін қалпына келтіру жүйесі

Starpenes kopējās rekonstrukcijas sistēma
Starpenes priekšējā laukuma rekonstrukcijas sistēma
Starpenes aizmugurējā laukuma rekonstrukcijas sistēma

Bendra dubens dugno chirurginio gydymo sistema
Priekinio priėjimo dubens dugno chirurginio gydymo sistema
Užpakalinio priėjimo dubens dugno chirurginio gydymo sistema

System for fullstendig reparasjon av bekkenbunnen
Reparasjonssystem for fremre bekkenbunn
Reparasjonssystem for bakre bekkenbunn

System pełny naprawy dna miednicy
System przedni naprawy dna miednicy
System tylny naprawy dna miednicy

Sistema de reparação do pavimento pélvico total
Sistema de reparação do pavimento pélvico anterior
Sistema de reparação do pavimento pélvico posterior

Sistem de reparație totală a planșeului pelvin
Sistem de reparație anterioară a planșeului pelvin
Sistem de reparație posterioară a planșeului pelvin

Система полной реконструкции тазового дна
Система реконструкции переднего отдела тазового дна
Система реконструкции заднего отдела тазового дна

Systém na rekonštrukciu celého panvového dna
Systém na rekonštrukciu prednej časti panvového dna
Systém na rekonštrukciu zadnej časti panvového dna

Sistema de reparación del suelo pélvico total
Sistema de reparación del suelo pélvico anterior
Sistema de reparación del suelo pélvico posterior

System för total reparation av bäckenbotten
System för reparation av främre delen av bäckenbotten
System för reparation av bakre delen av bäckenbotten

Total pelvik taban onarım sistemi
Ön pelvik taban onarım sistemi
Arka pelvik taban onarım sistemi

Система повної реконструкції тазового дна
Система реконструкції переднього відділу тазового дна
Система реконструкції заднього відділу тазового дна

Manufactured for:
ETHICON Women's Health & Urology
A division of ETHICON, INC.
a Johnson&Johnson company
Somerville, New Jersey 08876-0151

Made in Switzerland

EC
Legal Manufacturer
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P19074/J

Gynecare

PROLIFT+M™

Total Pelvic Floor Repair System
Anterior Pelvic Floor Repair System
Posterior Pelvic Floor Repair System

ENGLISH

Please read all information carefully.

Failure to properly follow instructions may result in improper functioning of the devices and lead to injury.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Training on the use of the GYNECARE PROLIFT+M™ Pelvic Floor Repair Systems is recommended and available and is similar to the training for the procedure using the GYNECARE PROLIFT™ Pelvic Floor Repair System. Contact your company sales representative to arrange for this training. Physicians should have experience in management of complications resulting from procedures using surgical mesh.

Refer to the recommended surgical technique guide for the GYNECARE PROLIFT™ Pelvic Floor Repair Systems for further information on the pelvic floor repair procedure. Contact your company sales representative to obtain this surgical technique guide.

The safety and effectiveness of the GYNECARE PROLIFT+M™ Systems compared to conventional surgical repair for pelvic organ prolapse have not been demonstrated in randomized controlled clinical trials. In the United States, substantial equivalence of the GYNECARE PROLIFT+M™ Systems to synthetic mesh with the same indication has been demonstrated through benchtop and cadaveric testing. Information on the clinical performance of mesh for pelvic floor repair is available in published literature. Contact your company sales representative for assistance.

INDICATIONS

The GYNECARE PROLIFT+M™ Total, Anterior, and Posterior Pelvic Floor Repair Systems, through placement of GYNECARE GYNEMESH M™ Partially Absorbable Mesh, are indicated for tissue reinforcement and long lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

CONTRAINDICATIONS

- **GYNECARE GYNEMESH M™ Mesh should not be used in infants, children, pregnant women, or women planning future pregnancies, as the mesh will not stretch significantly as the patient grows.**
- **GYNECARE GYNEMESH M™ Mesh must always be separated from the abdominal cavity by peritoneum.**
- **GYNECARE GYNEMESH M™ Mesh must not be used following planned intra-operative or accidental opening of the gastrointestinal tract. Use in these cases may result in contamination of the mesh, which may lead to infection that may require removal of the mesh.**
- **The GYNECARE PROLIFT+M™ Systems should not be used in the presence of active or latent infections or cancers of the vagina, cervix, or uterus.**

WARNINGS

- **Patients on anticoagulation agents undergoing surgery using the GYNECARE PROLIFT+M™ System must have their anticoagulation therapy carefully managed.**
- **Do not remove the GYNECARE PROLIFT™ Cannulas from the patient until the mesh implant has been properly positioned.**
- **A digital rectal exam should be performed to detect possible rectal perforation.**
- **Cystoscopy may be performed to confirm bladder integrity or detect possible bladder or ureteral perforation.**
- **Post-operatively the patient should be advised to refrain from intercourse, heavy lifting and/or exercise (e.g. cycling, jogging) until the physician determines when it is suitable for the patient to return to her normal activities.**
- **Use the GYNECARE PROLIFT+M™ Systems with care, and with attention to patient anatomy and to proper dissection technique, to avoid damage to vessels, nerves, bladder, bowel, and vaginal wall perforation. Correct use of the GYNECARE PROLIFT+M™ Systems components will minimize risks.**
- **Transient leg pain may occur and can usually be managed with mild analgesics.**

PRECAUTIONS

- **Users should be familiar with surgical procedures and techniques involving pelvic floor repair and synthetic meshes before employing the GYNECARE PROLIFT+M™ Systems.**
- **Avoid placing excessive tension on the mesh implant during placement.**
- **Do not manipulate the GYNECARE PROLIFT™ Retrieval Device with sharp instruments or cut it to alter its length.**
- **Do not affix the GYNECARE GYNEMESH M™ Mesh Implant with any staples, clips, or clamps as mechanical damage to the mesh may occur.**
- **This product should only be used under the prescription of a physician.**
- **In patients with compromised immune systems or other conditions that would compromise healing the risks and benefits should be carefully weighed.**
- **Vaginal or urinary tract infection should be treated and alleviated prior to implantation.**
- **Acceptable surgical practice should be followed for the GYNECARE PROLIFT+M™ Systems as well as for the management of infected or contaminated wounds. If the Mesh Implant is used in contaminated areas it must only be with the understanding that subsequent infection may require its removal.**
- **Prolapse repair may unmask pre-existing incontinence conditions.**
- **Prophylactic antibiotics can be administered according to the surgeon's usual practice.**
- **The use of this product with tissue adhesives is not recommended, as data are not currently available.**

ADVERSE REACTIONS

- **Potential adverse reactions are those typically associated with surgery employing implantable materials of this type, including hematoma, urinary incontinence, urinary retention/obstruction, ureter obstruction, voiding dysfunction, pain, infection potentiation, wound dehiscence, nerve damage, recurrent prolapse, inflammation, adhesion formation, fistula formation, contracture, scarring, and mesh exposure, erosion, or extrusion.**
- **Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT™ Guide passage and may require surgical repair.**
- **Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain or pain with intercourse. These may resolve with time.**
- **Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.**

CLINICAL PERFORMANCE

Randomized, controlled clinical evaluations of the GYNECARE PROLIFT™ System are underway, but at this time preliminary data are available from two early observational studies of transvaginal mesh that were initiated in 2004. These observational studies evaluated a pre-cut surgical mesh made of the same non-absorbable polypropylene as the mesh used in the GYNECARE PROLIFT™ System.

DESCRIPTION

The GYNECARE PROLIFT+M™ Total, Anterior, and Posterior Pelvic Floor Repair Systems consist of pre-cut GYNECARE GYNEMESH M™ Mesh implants and a set of instruments to facilitate mesh implant placement. The mesh implant is provided separate from the instruments, in a foil pouch with a paper folder designed for easy access of the mesh implant. The mesh implant may be trimmed while held in the paper folder. The following table summarizes the instruments included with each system:

REPAIR SYSTEM	COMPONENTS			
	Mesh Implant	Guide	Retrieval Devices	Cannulas
Total	1 Total	1	6	6
Anterior	1 Anterior	1	4	4
Posterior	1 Posterior	1	2	2

Table 1 – Components of the GYNECARE PROLIFT+M™ Pelvic Floor Repair Systems

GYNECARE GYNEMESH M™

GYNECARE GYNEMESH M™ Mesh is manufactured from approximately equal parts of absorbable poliglecaprone-25 monofilament fiber and non-absorbable polypropylene monofilament fiber. The polymer of the undyed and dyed polypropylene fiber (phthalocyanineblue, Color Index No.: 74160) is identical to the material used for dyed / undyed PROLENE® Polypropylene Suture material. Blue PROLENE® Suture monofilaments have been incorporated to produce contrast striping in the mesh. Poliglecaprone-25 fiber consists of a copolymer containing glycolide and ε-caprolactone; this copolymer is identical to the material used for MONOCRYL® (Poliglecaprone 25) Suture. The absorbable poliglecaprone part of the mesh aids handling, making intraoperative manipulation and positioning of the mesh easier. After absorption of the poliglecaprone-25 component, only the polypropylene mesh remains, which has burst strength of approximately 621 kPa (90 psi).

Total Implant

The Total Implant is constructed from GYNECARE GYNEMESH M™ Mesh and is shaped for performing a total vaginal repair. The Total Implant has six straps: four for securing the anterior portion of the implant via a transobturator approach and two for securing the posterior portion of the implant in the sacrospinous ligament via a transgluteal approach. Alternatively, the two posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The proximal and distal anterior straps have squared and triangular ends, respectively, while the posterior straps have rounded ends *(see Figure 1A)*.

Anterior Implant

The Anterior Implant is constructed from GYNECARE GYNEMESH M™ Mesh and is shaped for repair of anterior vaginal defects. The Anterior Implant has four straps that are secured via a transobturator approach. The proximal and distal anterior straps have squared and triangular ends, respectively *(see Figure 1B)*.

Posterior Implant

The Posterior Implant is constructed from GYNECARE GYNEMESH M™ Mesh and is shaped for repair of posterior and/or apical vaginal vault defects. The Posterior Implant has two straps that are secured in the sacrospinous ligament via a transgluteal approach. Alternatively, the two posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The posterior straps have rounded ends *(see Figure 1C)*.

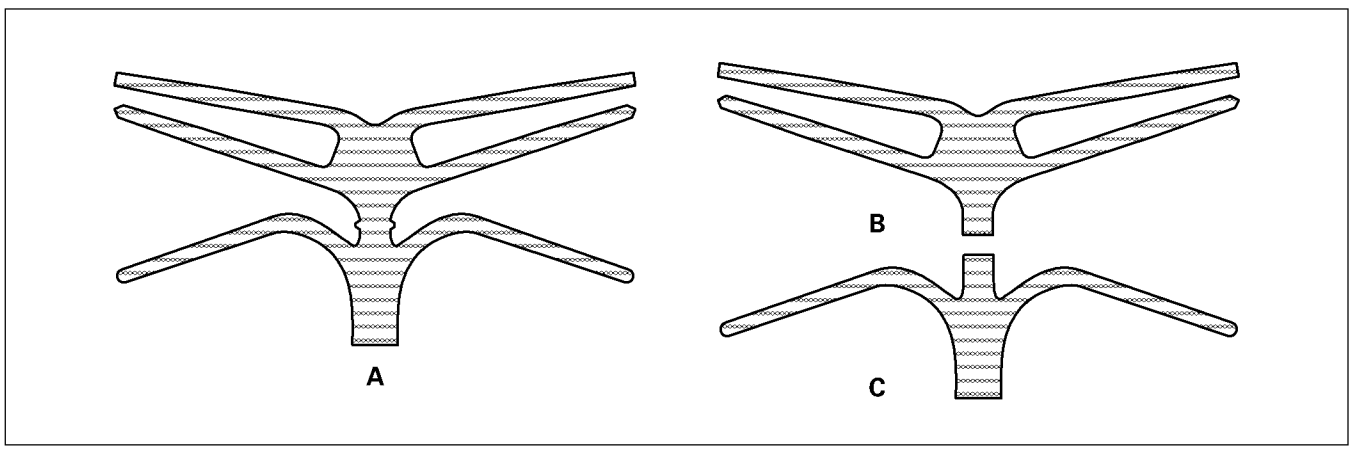

Figure 1 – Mesh Implants (Total, Anterior, Posterior)

GYNECARE PROLIFT™ Guide

The GYNECARE PROLIFT™ Guide is a single-patient-use instrument designed to create tissue paths to allow placement of the Total, Anterior, and Posterior Implants and to facilitate placement of the GYNECARE PROLIFT™ Cannula. Its length and curvature are specifically designed to create proper placement paths for all mesh implant straps. The GYNECARE PROLIFT™ Guide is suitable for use on both sides of the patient *(see Figure 2)*.

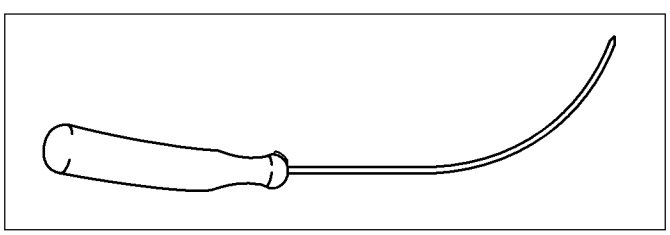

Figure 2 – GYNECARE PROLIFT™ Guide

GYNECARE PROLIFT™ Cannula
The GYNECARE PROLIFT™ Cannula is a single-patient-use instrument used in conjunction with the GYNECARE PROLIFT™ Guide to facilitate passage of the implant straps while protecting the surrounding tissue. Each GYNECARE PROLIFT™ Cannula is placed over the GYNECARE PROLIFT™ Guide prior to passage and remains in place after the GYNECARE PROLIFT™ Guide is withdrawn *(see Figure 3)*.

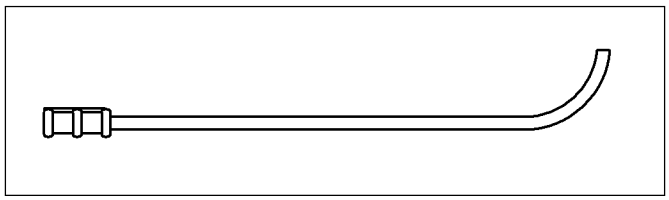

Figure 3 – GYNECARE PROLIFT™ Cannula

GYNECARE PROLIFT™ Retrieval Device
The GYNECARE PROLIFT™ Retrieval Device is a single-patient-use instrument designed to facilitate placement of the mesh implant straps. The GYNECARE PROLIFT™ Retrieval Device is passed through the previously positioned GYNECARE PROLIFT™ Cannula until its distal end is retrieved through the vaginal dissection. The distal end of the GYNECARE PROLIFT™ Retrieval Device has a loop to securely capture the mesh implant strap as the strap is drawn out through the GYNECARE PROLIFT™ Cannula *(see Figure 4)*.

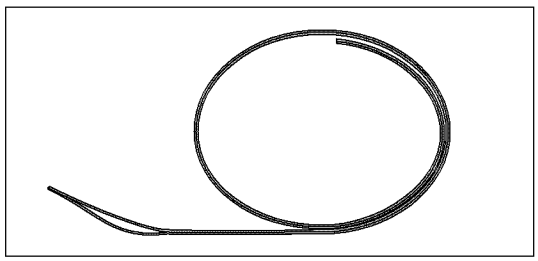

Figure 4 – GYNECARE PROLIFT™ Retrieval Device

PERFORMANCE
Animal studies show that implantation of GYNECARE GYNEMESH M™ Mesh elicits a minimum to mild inflammatory reaction which is followed by collagen tissue ingrowth through the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired.

In GYNECARE GYNEMESH M™ Mesh implanted subcutaneously in rats, the poliglecaprone-25 copolymer is essentially absorbed within 84 days after implantation. The polypropylene portion is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes. In an animal model, excessive connective tissue deposition and deleterious scar plate formation did not occur. The mesh construction permits trimming of the implant without unraveling.

STERILITY
The GYNECARE PROLIFT+M™ Systems are sterilized by ethylene oxide. DO NOT RESTERILIZE. DO NOT REUSE. Do not use if package is opened or damaged. Discard all opened, unused devices.

DISPOSAL
Dispose of the devices and packaging according to your facility's policies and procedures concerning biohazardous materials and waste.

STORAGE
Recommended storage conditions: controlled room temperature and relative humidity (approximately 25°C, 60% RH), away from moisture and direct heat. Do not use after expiry date.

INSTRUCTIONS FOR USE
NOTE: All figures below are not intended to provide any clinical teaching and only demonstrate the general use of each device.

Placement of the GYNECARE PROLIFT™ Cannula onto the GYNECARE PROLIFT™ Guide (See Figures 5A and 5B)

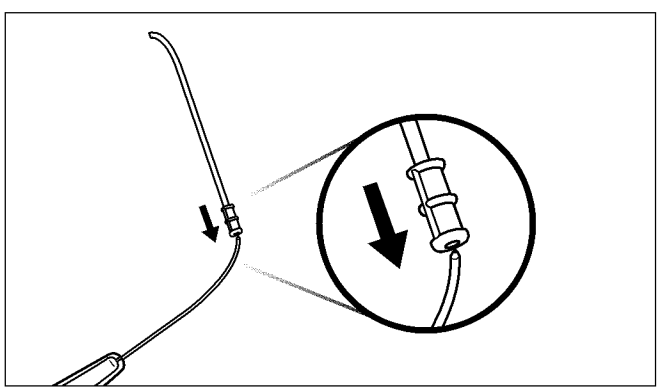

Figure 5A

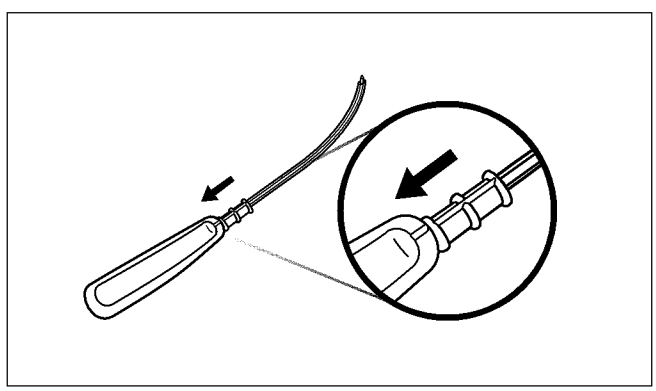

Figure 5B

IMPORTANT: Ensure proper alignment of GYNECARE PROLIFT™ Cannula and GYNECARE PROLIFT™ Guide upon assembly as demonstrated in Figure 5B.

Placement of the GYNECARE PROLIFT™ Cannula into the Patient (See Figures 6A, 6B, and 6C)

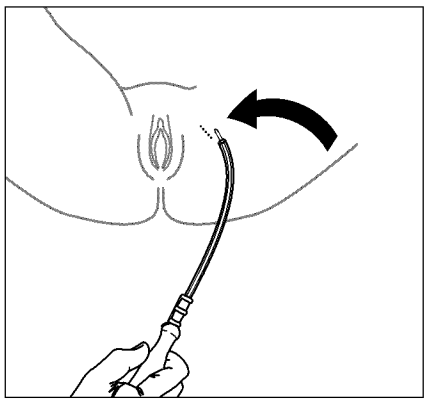

Figure 6A

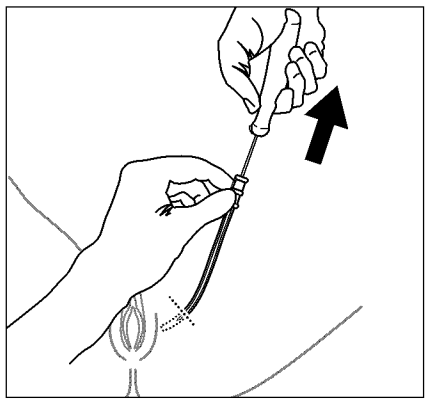

Figure 6B

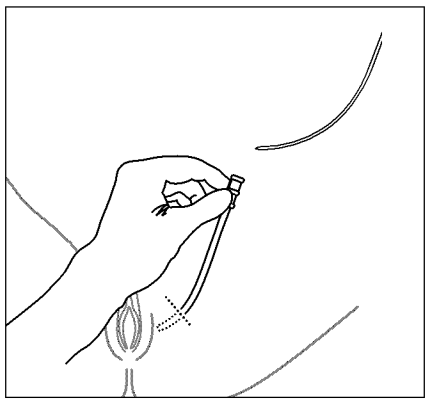

Figure 6C

Insertion and Passage of the GYNECARE PROLIFT™ Retrieval Device into the GYNECARE PROLIFT™ Cannula (See Figures 7A and 7B)

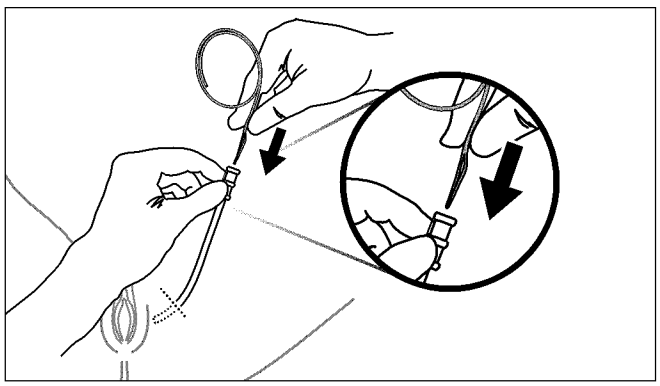

Figure 7A

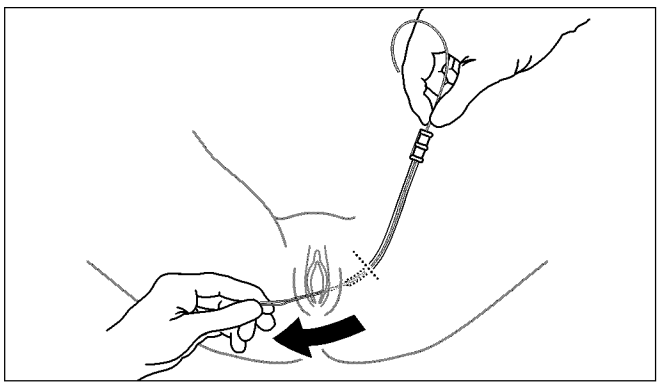

Figure 7B

IMPORTANT: **All provided GYNECARE PROLIFT™ Cannulas and GYNECARE PROLIFT™ Retrieval Devices should be placed prior to mesh implant installation.**

Capture of a Mesh Implant Strap with GYNECARE PROLIFT™ Retrieval Device (See Figures 8A, 8B, 8C)

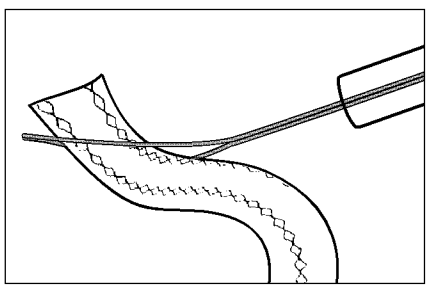

Figure 8A

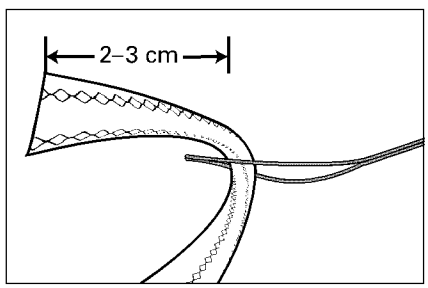

Figure 8B

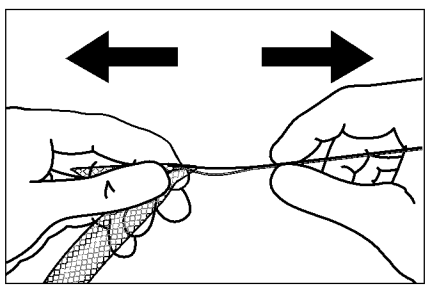

Figure 8C

Passage of a Mesh Implant Strap through the GYNECARE PROLIFT™ Cannula (See Figures 9A, 9B, 9C)

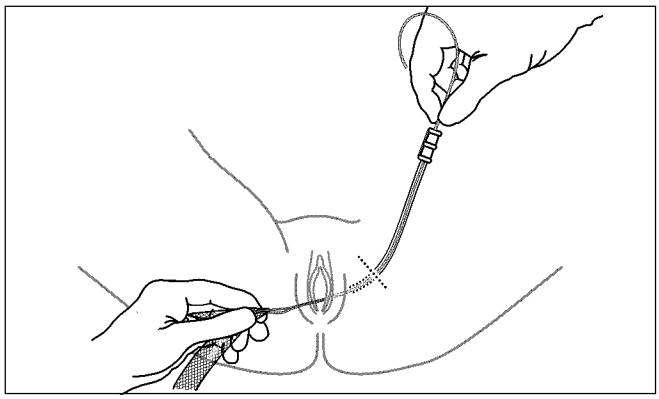

Figure 9A

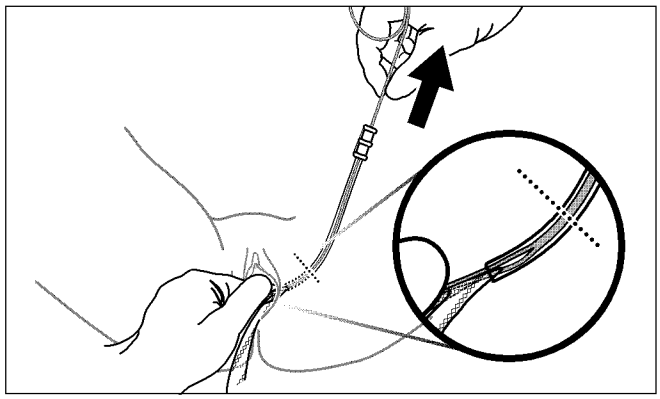

Figure 9B

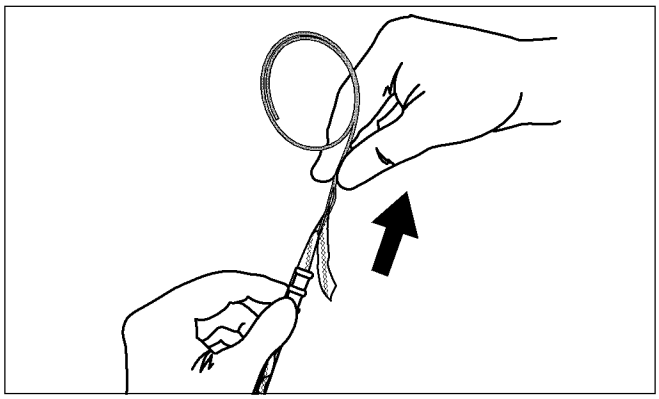

Figure 9C

IMPORTANT: Do not remove the GYNECARE PROLIFT™ Cannulas from the patient until the mesh implant has been properly positioned.
In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 1 cm (3/8") from the edge of the mesh.

HOW SUPPLIED
GYNECARE PROLIFT+M™ Systems are supplied in three different kits for Anterior, Posterior, or Total (Anterior + Posterior) pelvic floor repair. The GYNECARE GYNEMESH M™ Mesh implant is provided pre-shaped and sterile within a foil pouch. The GYNECARE PROLIFT™ Guide, the GYNECARE PROLIFT™ Retrieval Devices, and the GYNECARE PROLIFT™ Cannulas are provided sterile in a thermoformed tray, separate from the GYNECARE GYNEMESH M™ Mesh implant.

Symbols Used on Labeling